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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,849	11/26/2003	Jing Ma	549062000100	8161

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EXAMINER	
DUFFY, BRADLEY	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/722,849	MA ET AL.	
	Examiner	Art Unit	
	Brad Duffy	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-74* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12, 35-38, 63-66 and 73-74, drawn to antibodies or antibody fragments that inhibit the binding of a SM5-1 specific monoclonal antibody and/or bind specifically to a SM5-1 target antigen, classified in class 530, subclass 387.1.

II. Claims 13-30, drawn to isolated polynucleotides, vectors and cells containing said polynucleotides encoding antibodies, classified in class 536, subclass 23.1.

III. Claims 31-34, drawn to a method of producing an antibody, or a fragment thereof, classified in class 435, subclass 362.

IV. Claims 39-48, drawn to a method of treating neoplasm in a mammal using an antibody, classified in class 424, subclass 141.1.

V. Claims 49-50 and 52-54, drawn to a combination comprising an anti-neoplasm agent and antibodies or antibody fragments that inhibit the binding of a SM5-1 specific monoclonal antibody and/or bind specifically to a SM5-1 target antigen, classified in class 530, subclass 387.3

VI. Claims 51 and 55, drawn to a method of treating neoplasm in a mammal using an anti-neoplasm agent and an antibody, classified in class 424, subclass 138.1.

VII. Claims 56-62, drawn to a method of inducing caspase-10 mediated apoptosis in a cell in a mammal, classified in class 424, subclass 130.1.

VIII. Claims 67-72, drawn to a method for assaying for human SM5-1 target antigen in a sample, classified in class 435, subclass 7.23.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I-II and V represent separate and distinct products, which are made by materially different methods, and are used in materially different methods, which have different modes of operation, different functions and different effects. The antibodies of Group I, the polynucleotides of Group II and the antibody/anti-neoplasm agent combination of Group V are structurally and chemically different from each other. A polynucleotide's structure is comprised of linear, contiguous nucleotides with variable structure, an antibody's structure is comprised of linear, contiguous amino acids that fold into a specific three-dimensional structure and an anti-neoplasm agent structure is undefined, but includes a diverse genus of structures from small molecules to polypeptides. The antibody is raised by immunization, the polynucleotide is made by nucleic acid synthesis and an anti-neoplasm agent could be made by a diverse array of processes, i.e. chemical synthesis or translation of mRNA. Furthermore, the antibody can be used for purifying antigen, the polynucleotide can be used for hybridization screening, and the anti-neoplasm agent can be used for methods of treatment. Additionally, the invention of Group V requires an anti-neoplasm agent, which is not required by any of the other groups. The examination of all groups would require

different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus, the inventions of Groups I-II and V are patentably distinct.

The methods of inventions of Groups III-IV and VI-VIII differ in the method objectives, method steps and parameters and in the reagents used. The invention of Group III recites a method of producing an antibody or antibody fragment recombinantly. The inventions of Group IV and VI-VIII recite methods of using an antibody to treat neoplasm, using an anti-neoplasm agent and antibody to treat neoplasm, using an antibody to induce apoptosis, or using an antibody to assay for SM5-1 antigen, respectively. Therefore, the methods of inventions of Groups III-IV and VI-VIII differ in the method objectives, method steps, parameters and reagents used. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus, the inventions of Groups III-IV and VI-VIII are separate and distinct in having different method objectives, method steps, parameters, reagents used and different endpoints and are patentably distinct.

Inventions of Group I and Group III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the antibody fragments of Group I could be made by a cell-free system method, such as an *in vitro E. coli* cell-free

translation system, which is materially different process than the cell-dependent system method claimed in Group III and is therefore distinct.

Inventions of Group I and Group IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the antibody of Group I could be used in a materially different process such as purifying the antigen, or the materially different process of inducing apoptosis of Group V, or the materially different process of assaying for the antigen of Group VI, which differ in the method objectives, method steps and parameters from the method of treating neoplasm of Group IV and are therefore distinct.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different classifications, restriction for examination purposes as indicated is proper.

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if

the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Duffy whose telephone number is (571) 272-9935. The examiner can normally be reached at Monday through Friday from 7:00 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
Brad Duffy
571-272-9935

David Blanchard
AU 1643